

The Tam-Gel Study: A Randomized, Double-blind, Placebo-controlled Study of 4-hydroxytamoxifen Topical Gel in Women with Mammographically Dense Breast

Why is this study being done?

The purpose of this study is to see if a tamoxifen gel used daily on breasts may help prevent breast cancer. Tamoxifen when taken as a pill can be used to help prevent breast cancer. Some women can have problems with taking the pill due to its possible side effects, like hot flashes.

Researchers are hoping to see if using tamoxifen as a gel will have the same positive effects as the pill, but with fewer side effects. This will be done by comparing people using tamoxifen gel to people using a gel without tamoxifen (placebo).

Who can participate in this study?

To participate in the study, you must:

- Be an adult woman age 40-69;
- Have dense breasts previously identified by mammogram;
- Be willing to apply the gel to your breast(s) every day for 1 year

What will happen if you join the study?

If you join the study, you will be asked to:

- Have blood drawn for testing and research;
- Allow the study team to access to your medical records;
- Apply gel to your breast(s) every day for 1 year;
- Have phone calls every 3 months with the study team to discuss your progress;
- Return to the clinic 6 months and 12 months after you start using the gel for evaluation.

How long is the study?

You will use the gel for one year and have a final clinic visit for the study at that time. Your mammogram from the year after you complete the study will be collected for research to look for any long-term changes from the gel.

How do I get more information?

If you, a friend, or a family member wish to participate in or learn more about the study, please contact:

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